

## REMARKS

Claims 1 and 3-12 were pending. Claims 10-12 are withdrawn as directed to a non-elected invention. Claims 1 and 3-9 stand rejected. Dependent claims 13 to 16 are added.

Applicants thank Examiner Lucas for the courtesy of a personal interview on November 30, 2005. A summary of the interview is filed with this response.

### Rejections under 35 U.S.C. § 112

*Item 6.* Applicant notes that the rejection under 35 U.S.C. § 112(2), of claims 3 and 4 is withdrawn.

*Item 8.* The Examiner rejected claims 3-9 under 35 U.S.C. § 112(1) because the specification, while enabled for immunogenic compositions comprising an inactivated influenza virus, does allegedly not reasonably provide enablement for vaccine compositions, or compositions inducing immunity against any viral pathogen. The claims as amended indicate that the host is in need of the immune response, and as there would be no such "need" unless the response induces a therapeutic effect, the rejection is maintained on the same grounds previously described. The rejection is withdrawn from claim 4 as this claim is currently under consideration only to the extent that it reads on the elected invention (influenza virus antigens).

The Examiner states that the examples that show a therapeutic effect are unclear whether (1) a common means of producing the antigens was used or (2) what the components or means of producing each of the indicated antigenic compositions is. Applicants note that the Examiner finds that the Declaration shows some efficacy in chickens. Furthermore, the application "appears enabled for the immunization against influenza using the claimed compositions." Page 4.

Applicants have amended claims 3 and 5 to remove the "need" phrases.

Applicants respectfully assert that the specification provide ample enablement of the compositions of the invention. Indeed, preparation of a composition and immunogen for baculovirus is found in Example 13 and the bulk preparation is Example 12. Preparation of a composition and immunogen for human immunodeficiency virus is

found in Example 11 showing clinical results. Moreover, a Declaration of record supported the efficacy of this Example in numerous published scientific articles. One of the articles showed a very statistically significant reversal of wasting in subjects treated with the anti-HIV composition and immunogen of the invention. The specification also provides Example 15, directed to preparation of a composition and immunogen for influenza. This Example was further supported by a previously presented Declaration showing improved resistance to avian flu in chicks treated with the anti-H5N1 influenza composition and immunogen of the invention. Example 32 provides details for the preparation of an anti-rabies composition and immunogen. Example 34 is directed to preparation of an anti-cytomegalovirus composition and immunogen. Considering the complexity of the task of making an effective immunogen, the providing of five Examples should be more than enough to enable anyone of ordinary skill in the art to prepare the whole claimed range of immunogens and viral compositions. In contrast to the Examiner's assertions, the specification recites multiple examples for preparing the claimed compositions. For at least these reasons, withdrawal of the rejection of claims 3-9 under §112(1) is respectfully requested.

Solely to speed prosecution, claim 3 is amended to recite the five exemplary viral pathogens. Claim 3 as amended and new dependent claim 15 are narrowly drawn to the recited viral compositions and immunogens, respectively. Moreover, new claims 14 and 16 are drawn to influenza.

#### **Rejections under §102.**

*Item 10.* Applicants note the withdrawal of rejection of claims 1 and 2 as anticipated by Avtushenko et al.

*Item 11.* Applicants note the withdrawal of rejection of claims 3-5 and 7-8 as anticipated by Barrett et al.

*Item 12.* Applicants note the withdrawal of rejection of claims 5-8 as anticipated by Waldman et al.

#### **Rejections under §103.**

*Item 14.* Applicants note the withdrawal of rejection of claims 1-9 as obvious over Zakay-Rones or Dutcher et al.

*Item 15.* Applicants note the withdrawal of rejection of claims 5-9 as obvious over Sokoll.

*Item 16.* Applicants note the withdrawal of rejection of claim 9 as obvious over Barrett, Avtushenko or Waldman.

*Item 17.* In a new rejection, claim 1 stands rejected under §103 as obvious over Meruelo et al.

Meruelo et al. is directed to a process of inactivation of a virus with hypericin and related compounds. Col. 3, ll. 1-2. Meruelo et al. extensively discusses the use of hypericin and hypericin analogs. Col. 3, l. 1 to col. 4, l. 43. Use of a heat treatment is disclosed only in combination with a hypericin (or analog) treatment. "[T]he above method [hypericin treatment] further comprises inactivating the agent by treating with formaldehyde or glutaraldehyde, by heat treatment, by treatment with acid pH, or with heavy metal salts . . ." Col. 4, ll. 44-47. (Emphasis added.) The Examiner points to text disclosing the heat inactivation. Col. 12. However, it is crucially important to note that the Meruelo et al. method is "performed in the presence of neon light." Col. 12, ll. 33-34. The use of neon light is an unambiguous reminder that the photosensitizer hypericin (or an analog) must be used in Meruelo's method. Thus, one of skill in the art would not use Meruelo's teaching of hypericin use to devise the heat-inactivation method of the present invention.

Moreover, one of ordinary skill in the art would not use hypericin in the doses taught by Meruelo et al. because it causes death. See, for example, Poisonous Plants of Pennsylvania, <http://cal.vet.upenn.edu/poison/agbook/hellebor.htm> which describes St. John's wort, which produces hypericin, in these graphic terms: "Animals may experience convulsions prior to death" and "Blindness and starvation may precede death." Thus, one of skill in the art would not rely on Meruelo's teaching to prepare a multivalent vaccine, a composition for eliciting an immune response, or an immunogen. For at least this additional reason, Meruelo et al. would not render claim 1 unpatentable. Withdrawal of the rejection is respectfully requested.

*Item 18.* Claims 3-9 are rejected under §103 as obvious over Meruelo et al. in view of Felici et al. or Ooyama et al., which are of record.

Felici et al. and Ooyama et al. are relied upon by the Examiner merely to provide support for the concept of making immunogens and compositions in the form of pills. Neither reference discloses the composition and immunogen of the invention.

Withdrawal of the rejection of claims 3-9 is respectfully requested for at least the reasons presented above.

#### Conclusion

New claims 13-16 are added. Support for these claims is found in the claims and specification as originally filed, including, for example, the specific Examples cited above. No new matter is added.

Entry of the amendment is respectfully requested. A petition for a three month extension of time and fee accompanies this Amendment. If payment of other fees is required to keep the application pending, the Director is authorized to debit account no. 22-0185, or to credit the account for any overcharges.

The Examiner is urged to directly contact the undersigned at 202-331-7111, if doing so would speed allowance of the claims.

Sincerely,

Date: Feb. 23, 2006



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